

Martin, Barb

From: Bleser, Mike <mike.bleser@walgreens.com>
Sent: Friday, November 09, 2012 2:14 PM
To: Murray Jr, Denman; Martin, Barb; Destefano, Frank
Subject: FW: November 8th DEA meeting at NABP

FYI

From: Madarasz, Anika
Sent: Friday, November 09, 2012 1:28 PM
To: Thoss, Sue; Bleser, Mike; Provost, Kristie; Trotz, Sherrise; Svihra, Ed; Platts, Debbie; Stukel, Raymond
Subject: FW: November 8th DEA meeting at NABP

Thank you,
Ani

Cell 224.548.6702

From: Swords, Rex
Sent: Thursday, November 08, 2012 9:53 PM
To: Crawford, Kermit
Cc: Hansen, Suzanne; Lovejoy, David; Polster, Tasha; Pinon, Dwayne; Zagami, Patty
Subject: November 8th DEA meeting at NABP

I have the sense that today's meeting was a condensed version of the regional meetings the DEA is holding throughout the country for pharmacists. Although no attendance list was available, I believe most, if not all, major chain operators were present at the meeting: CVS, Walmart/SAMS, Riteaid, Safeway, Kroger, Giant Eagle, Kmart to name a few and approximately 50 people in total.

There were also several Executive Director's of BOP's present (Kentucky, Louisiana)

Joseph Ranazzisi (attorney and pharmacist)
Deputy Assistant Administrator
Office of Diversion Control

Mr. Ranazzisi presented a large Power Point deck on "Prescription Drug Trafficking and Abuse" for approximately 2 hours
Comments:

- The DEA views Chain and Independent the same. They have heard the complaints from chain that they believe the DEA is focused on chain and not independents and he dismisses that notion.
- "Chains come up to the Hill and say the DEA is targeting them"
- The DEA targets violation, not business types
- "A pharmacist is a professional and they shouldn't be filling every prescription that comes through the door"
- Believes that pressure from owners/operators to fill scripts is driving the problem
- If this continues they won't be just accessing civil penalties, there may be criminal penalties
- More people die from benzodiazepines than heroin and cocaine

- Verbalized that the new 21CFR 1306.04 for Carisoprodol and Oxycodone
- Carisoprodol is being replaced with cyclobenzaprine (Flexeril)
- Oxycodone is being replaced with oxymorphone (Opana)
- Reviewed 21CFR 1301.74
 - The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual nature
- If suspicious – you don't ship. Decreasing the order and shipping is not complying with the regulation
- Ignoring suspicious orders will result in civil penalties. Cited Cardinal, ABC and McKesson fines
- Reviewed 21CFR 1306.04 (a)
 - "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice"
 - Referenced case law of United States V. Moore 432 US 122 (1975)
- Pharmacists – last line of defense
 - "The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription" 21 CFR 1306.04 (a)
- In 2010, 43% of all oxycodone 30mg products were dispensed in Florida
- "In Florida, the drug distribution system has collapsed"
- In 2012 in Florida
 - 91 actions taken
 - 50 orders to show cause
 - 21 ISO's
 - 85 surrenders of license from independents
- Asked attendees to review the website EROWID
- ONDCP Strategy
 - Education
 - Tracking and monitoring
 - Proper disposal
 - Enforcement
- Reminded the attendees that "take back" programs for controlled substances are illegal
- Red Flags
 - Many customers that pay cash for their prescriptions
 - Always write for the same medication combination – no variation to account for different conditions or size
 - Same diagnosis code for every prescription
 - Long distances for prescriber or patients
 - Customers coming in groups, each with the same prescriptions issued by the same physician
 - Customers with prescriptions for controlled substances out of scope for the prescriber – dentists, podiatrists, pediatricians
- "If a pharmacist does his job, we wouldn't have this problem"
- Looking for a company to do it's job in this area
- Hearing complaints from pharmacists that they don't have time to check all these prescriptions for good faith. Wants to make sure chains aren't inhibiting this by pressuring their pharmacists to fill fast or not providing adequate labor
- Believes that all hydrocodone is a BIG problem and that it should be schedule 2.
- Believes that compensation (bonus) should not be tied to prescription volume of controlled substances

Alan Santos

Associate Deputy Assistant Administrator, Office of Diversion Control

Mr. Santos spoke on the Methamphetamine Problem

Comments:

- CMEA - Combate Methamphetamine Epidemic Act
- Debate is around tracking vs controlling

- Cited stores that sell an excessive amount of product

John Partridge
Chief, Liaison Policy Office

Mr. Partridge spoke on a number of subjects

Comments:

- Time / productivity requirements are a concern
- Bonus parameters are a concern
- The fax process for controlled substances prescriptions that present a mocked up Rx for a physician signature is not allowed by regulation. (Omnicare issue)
- Shortages – DEA issues quota for raw product – not dosage forms or strengths. Shortages are not their issue.
- Employee theft
 - Must report with one business day of discovery
 - Should report all thefts to the local law enforcement agency and BOP
 - Would prefer that DEA 106 is completed on-line
 - Only 4% of DEA registrants are pharmacies, but 65.8% of all thefts occur at a pharmacy
 - * Do we need better security, storage, etc requirements?
 - Need to look at deterrence and make it difficult for theft to occur and minimize product loss
 - Do not think safes are a good response to the problem and prefer dispersion of product

The team will review the comments and make appropriate recommendations to address where necessary.

Thank you,

Rex Swords, R.Ph.
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